

Appl. No. : 10/634,213
Filed : August 5, 2003

REMARKS

The present Amendment is responsive to the Examiner's Office Action dated October 2, 2006. By way of summary, Claims 1-52 were pending in this application, with Claims 1-4, 13, 14, 33, 34, and 40-51 previously withdrawn from consideration. In this Amendment, Claims 1-4, 10, 13, 14, 33, 34, and 40-51 have been canceled, Claims 5, 12 and 32 have been amended, and new Claims 53-60 have been added. Accordingly, Claims 5-9, 11-12, 15-32, 35-39 and 52-60 remain pending.

Allowed Claims and Allowable Subject Matter

Applicants appreciate the Examiner's indication of allowability of Claims 27, 28 and 37, and of Claim 12 if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

Claim Amendments and New Claims

In this Amendment, Claim 5 has been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. Claim 5 has been amended to incorporate the some of the subject matter of dependent Claim 12 and intervening Claim 10. Claim 10 has been canceled and Claim 12 has been amended accordingly.

Claim 32 has been amended to further define a method that now recites, in part, "making an incision into a naturally occurring space of an eye." "inserting an instrument through the incision" and "serially dispensing a plurality of preloaded implants from the instrument into eye tissue at a respective plurality of locations within the eye... without requiring removal of the instrument from the incision."

New Claims 53-60 have been added and are directed to, *inter alia*, a plurality of biocompatible implants positioned in the elongate body, wherein at least one of said implants comprises a cutting member. Support for these claims may be found, for example, in paragraph [0145] of the specification.

The Applicants respectfully submit that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. The above-referenced claims, however, have been amended without altering their scope in order to clarify the features of the Applicants' inventions. These claim amendments are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the

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entry of such amendments. Applicants reserve the right to pursue claims of the same or broader scope in a continuation application and respectively submit that the pending claims are now in a condition for allowance.

Response to the Rejections under 35 U.S.C. §102(b)

1. Claim 32

The outstanding Office Action rejected Claim 32 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,050,999 to Paraschac et al. According to the Examiner, "Paraschac discloses a method of treating an eye condition (hyperopia) including the steps of serially dispensing a plurality of preloaded implants 40 from an instrument 50 to a plurality of locations within the eye."

In contrast to the disclosure and teachings of Paraschac, independent Claim 32, as amended, now recites, in part, "making an incision into a naturally occurring space of an eye," "inserting an instrument through the incision" and "serially dispensing a plurality of preloaded implants from the instrument into eye tissue at a respective plurality of locations within the eye... without requiring removal of the instrument from the incision." By utilizing a naturally occurring space of an eye, a plurality of implants may be dispensed at a plurality of locations within the eye without the increased risk associated with excessive cutting. Applicants respectfully submit that Paraschac does not disclose any procedure whereby an incision is made into a naturally occurring space of the eye. Indeed, Paraschac only discloses making incisions from the outer periphery of the anterior surface of the cornea or limbus of the eye and inserting implant into pockets created by separating the stromal layers of the cornea using a blade (Col. 8, line 67 to Col. 9 line 3). None of these locations involve naturally occurring spaces of the eye as required by amended Claim 32.

Accordingly, Applicants respectfully submit that independent Claim 32, as amended, is not anticipated by Paraschac and respectfully request the anticipation rejection based on Paraschac to be withdrawn.

2. Claims 5-7, 10, 11, 13 and 14

The outstanding Office Action rejected Claims 5-7, 10, 11, 13 and 14 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,833,694 to Poncet. As Applicants have amended Claim 5 to incorporate the allowable subject matter of Claim 12 and intervening Claim

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10, Applicants have no occasion to comment on this rejection. Claims 6-9, 11 and 13-14, which depend from Claim 5, are patentable for the same reasons that Claim 5 are patentable, and are also patentable for the unique combination of features that each claim recites.

Response to the Rejections under 35 U.S.C. §103

The outstanding Office Action rejected Claims 5-11, 15-26, 29-31, 35, 36, 38, 39 and 52 under 35 U.S.C. §103 as obvious over U.S. Patent Pub. No. 2003/0088260 to Smedley et al. (or U.S. Patent No. 6,533,768 to Hill in view of Smedley) in view of Poncet or Paraschac or U.S. Patent No. 6,530,896 to Elliot. According to the Examiner, neither Smedley nor Hill disclose “the placing of multiple implants into the body and serially dispensing them into claimed location in the eye” (October 2, 2006 Office Action, pg. 4) and therefore the Examiner relied upon a combination with the other cited references to teach “a dispensing body used to dispense a plurality of implants into a patient’s body.” The Examiner asserted that it would have been obvious to one of skill in the art to provide “duplicates of known elements” to “allow for faster recovery time and would also allow for quicker removal of fluid from the eye which is a cause of glaucoma.” *Id.*

Applicants respectfully disagree with the Examiner’s contention that one of skill in the art would be motivated to combine the cited references, as none of the references cited by the Examiner disclose or suggest a motivation to insert multiple implants to reduce intraocular pressure (IOP). Furthermore, there is no motivation to insert multiple implants reduce IOP because the prior art reflected competing teachings that (1) excessive reductions in IOP may occur, or that (2) backpressure in the drainage system of the eye may limit further reductions in IOP, and thus the use of multiple implants would (3) incur additional surgical risks of complications and delayed recovery without clear benefits.

Poncet, for example, is directed to the placement of multiple cardiovascular stents to treat multiple sites within a body passage. (Poncet, Col. 2, ln. 6-10). The solution presented in Poncet addresses the multi-site nature of the cardiovascular problem as identified by Poncet.

Similarly, Paraschac is directed to multiple corneal implants to adjust corneal curvature and to correct vision abnormalities. (Paraschac, Col. 1 ln. 62-65). As one can imagine, without the use of multiple implants to maintain proper corneal symmetry, the resulting vision would be

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distorted. In Paraschac, the nature of the vision correction also requires multi-site solution to achieve its intended result.

Finally, Elliot discloses the use of time-releasing implants to achieve release of drug over a significant period of time, and that single or multiple implants may be used. (Elliot, Col. 1, ln. 23-35; Col. 2, ln. 52-62).

Thus, while each of these references suggest a problem-specific teaching to use multiple implants, none of the cited references disclose or suggest a motivation to insert multiple implants to reduce intraocular pressure (IOP). Furthermore, one of ordinary skill in the art would not be motivated to insert multiple IOP implants for several reasons.

First, it is known to those of ordinary skill in the art that excessive reductions in IOP, known as hypotony, may also occur. See, for example, the patent references disclosed in the specification of Hill in Col. 3, ln. 31-59, such as U.S. Pat. No. 4,037,604 to Newkirk at Col. 1, ln. 13, or U.S. Pat. No. 6,007,510 to Nigam at Col. 2, ln. 15-21. For this reason, one of ordinary skill in the art would not be motivated to insert multiple IOP implants to “allow for a quicker removal of fluid from the eye” as suggested by the Examiner.

Second, it has been hypothesized that IOP implants draining into the episcleral aqueous veins may eliminate the risk of hypotony maculopathy because of the “backpressure that would prevent the eye pressure from going too low.” (Col. 2, ln. 20-24 in U.S. Pat. No. 6,638,239, and in the instant application at paragraph [0026]; *See also* Hill). These references also fail to motivate one of ordinary skill in the art to insert multiple IOP implants because these references suggest that backpressure in the episcleral aqueous veins may limit additional reductions in IOP from multiple implants. Thus, there is uncertainty among those of ordinary skill in the art concerning the benefits of inserting additional implants into the eye to treat glaucoma.

Third, one of ordinary skill in the art would also likely be concerned about the increased risk to the patient from inserting multiple implants, which is further compounded by the uncertain outcome as described above. Therefore, Applicants also disagree that numerous implants “would allow for faster recovery time” as stated by the Examiner. (October 2, 2006 Office Action, pg. 4).

Inasmuch as Smedley or Hill does not disclose, teach, or suggest a plurality of biocompatible implants that are sized and shaped to convey aqueous humor from the anterior

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chamber to a fluid outflow path of the eye so as to reduce elevated intraocular pressure and, as explained above, one of skill in the art would be motivated to combine the teachings of Paraschac, Poncet nor Elliot with those of glaucoma treatment, the combination of teachings of the cited references would be improper. Applicants respectfully request indication of allowance of independent Claims 5, 15, 26-32, 40 and 52-53.

Likewise, the dependent Claims 6-9, 11, 16-26, 29-31, 35, 36, 38, and 39 of the respective independent claims are patentable for at least the same reasons that their independent claims are patentable, and also for the unique combination of features that each claim recites. Accordingly, Applicant respectfully submit that Smedley, Hill, Paraschac, Poncet and Elliot do not render these dependent claims obvious, and also request withdrawal of the obviousness rejection of these claims.

Conclusion

In view of the foregoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. Applicants have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: 

Walter S. Wu
Registration No. 50,816
Attorney of Record
Customer No. 20,995
(949) 760-0404

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